



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/675,610

09/29/2003

Carla Rosa Pienknagura

ACS 64021

6355

24201

7590

10/23/2006

FULWIDER PATTON

6060 CENTER DRIVE

10TH FLOOR

LOS ANGELES, CA 90045

EXAMINER

WEBB, SARAH K

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---|--|
| Office Action Summary | Application No. 10/675,610 | Applicant(s) PIENKNAGURA, CARLA ROSA | |
| | Examiner Sarah K. Webb | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3 and 5-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,679,911 to Burgermeister in view of US Patent No. 5,695,516 to Fischell et al.

See Figures 7A and 7B of Burgermeister. The stent has a plurality of flexible rings (310), and the proximal and distal rings have apertures defined by second peaks (332) attached to first peaks (334). Burgermeister explicitly states that the apertures enlarge when the stent expands (column 7, lines 48-52). The stent is metallic (column 2, line 9). Any part of the stent may have a variable thickness (column 4, lines 16-21 and column 9, line 15 through column 10). The stent may include a drug (column 4, lines 20-22).

Burgermeister fails to state that the stent of Figures 7A and 7B has a greater expanded length than unexpanded length, but does state that it does not forshorten during expansion (column 3, lines 22-34). Burgermeister does teach that a stent structure can be modified so that the stent lengthens upon expansion (column 3, lines 50-54). Fischell teaches that stent can be configured to lengthen upon expansion to ensure complete coverage of a stenosis (column 1).

As discussed above, the apertures defined by second peaks (332) attached to first peaks (334) enlarge when the stent expands (column 7, lines 48-52). Combining the lengthening apertures with a stent structure that does not shorten upon expansion would result in a lengthening stent. The embodiment in Figure 3A

Art Unit: 3731

maintains a substantially constant length in expanded and compressed configurations (column 6, lines 13-24). This stent has a similar basic structure to the stent disclosed in the instant application, having undulating rings with links connecting distal peaks of adjacent rings. Even though the peaks are slightly out of phase in Figure 3A, Burgermeister explains that the peaks align upon expansion (column 3, lines 55-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the lengthening apertures and non-forshortening stent structure of Burgermeister in order to obtain a stent that lengthens upon expansion, as Fischell teaches that this helps to ensure that a stenosis is completely covered.

Regarding claims 9 and 10: the limitations "formed from a tube" and "formed from a sheet" are considered to be product by process limitations. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Therefore, these claims are not given patentable weight.

Regarding claims 12-16: Burgermeister fails to disclose specific metal alloys for forming the stent, such as nickel-titanium, but this is a common material used for forming stents and is well known in the art.

Regarding claims 28-31, Burgermeister states that the stent can be delivered by balloon catheter (column 5, line 10) but does not specify the location of the ends of the stent to the balloon shoulder. It is considered to be an obvious matter of design choice to change the balloon length to accommodate for a different stent length, since such a modification would have involved a mere change in size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Response to Arguments

2. Applicant's arguments filed 8/3/06 have been fully considered but they are not persuasive. Applicant argues that the adjacent rings in the embodiment of Figures 7A and 7B in Burgermeister are connected peak to valley and shorten during expansion. As pointed out above and in the previous action, the embodiment in Figure 3A maintains a substantially constant length in expanded and compressed configurations (column 6, lines 13-24) by connecting peaks to peaks (or valleys to valleys). This stent has a similar basic structure to the stent disclosed in the instant application.

Therefore, Burgermeister discloses both a configuration of interconnected rings that maintains its length during expansion and apertures that lengthen upon expansion.

3. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Fischell describes the advantages to a stent structure that lengthens upon expansion as overcoming problems with incomplete coverage of a dilated stenosis (see column 1). This teaching is combined with the Burgermeister stents, which include apertures that lengthen upon expansion. Burgermeister also suggests a stent structure that lengthens upon expansion in lines 50-54 of column 3. One of ordinary skill in the art would be motivated to combine the teaching of Fischell with the structures disclosed by Burgermeister to make a stent that lengthens upon expansion.

Art Unit: 3731

4. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW

10/12/06



JULIAN W. WOO
PRIMARY EXAMINER